



United States
Department of
Agriculture

Animal and
Plant Health
Inspection
Service

Biotechnology
Regulatory
Services

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Dr. Minako Sumiyoshi
Sanatech Seed Co., Ltd.
Landic Toranomom Bldg. 7F, 3-7-10 Toranomom,
Minato-ku, Tokyo 105-0001 Japan

Re: Confirmation of the regulatory status of genome edited tomato with increased γ -aminobutyric acid (GABA)

Dear Dr. Sumiyoshi,

Thank you for your letter dated May 19, 2020 inquiring whether the tomato (*Solanum lycopersicum*) product described in your letter is a regulated article under 7 CFR part 340. Your letter describes the transformation of tomato with CRISPR-Cas9 reagents, resulting in a genome edited tomato line with increased γ -aminobutyric acid (GABA) content.

The Plant Protection Act (PPA) of 2000 gives USDA the authority to oversee the detection, control, eradication, suppression, prevention, or retardation of the spread of plant pests or noxious weeds to protect the agriculture, environment, and economy of the United States.

USDA regulates the importation, interstate movement and environmental release (field testing) of certain organisms developed using genetic engineering that are, or have the potential to be, plant pests under 7 CFR part 340, "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason To Believe Are Plant Pests." Under the regulations, an organism is deemed a regulated article if it has been genetically engineered using a donor organism, recipient organism, or vector or vector agent that is listed in § 340.2 and meets the definition of a plant pest; or that is an unclassified organism and/or an organism whose classification is unknown, or if the Administrator determines that the organism is a plant pest or has reason to believe it is a plant pest.

In your letter, you describe the use of *Agrobacterium* to introduce a construct containing CRISPR-Cas9 nuclease and sgRNA into tomato with the intent to delete the Calmodulin binding domain (CaBD) of a glutamate decarboxylase gene (GAD) in order to produce tomatoes with increased levels of GABA. You state that genome edited tomato lines were obtained by self-pollination and that Polymerase Chain Reaction (PCR) was used to establish that all construct DNA was removed from the final genome edited tomato line.

Based on the representations you made in your letter, including your description of the results of your confirmation methods, your genome edited tomato line is not itself a plant pest and no plant pest sequences were integrated into the plant genome of tomato. Consistent with previous responses to similar letters of inquiry, USDA does not consider your genome edited tomato line to be regulated pursuant to 7 CFR part 340.

Although your genome edited tomato line is not regulated under 7 CFR part 340, other regulatory authorities may apply. For example, the importation of your tomato seeds or plants will be subject to applicable Plant Protection and Quarantine (PPQ), permit and/or quarantine requirements. For further information, should you plan to import these tomato seeds or plants, you may contact the PPQ general number for such inquiries at 877-770-5990. To inquire about the regulatory status of your product with the Environmental Protection Agency (EPA), please contact Alan Reynolds at 703-605-0515. To inquire about the regulatory status of your product with the Food and Drug Administration (FDA), please contact PlantBiotech@fda.hhs.gov.

Should you become aware at any time of any issues that may affect USDA's conclusion regarding this inquiry, you should immediately notify us in writing of the nature of the issue.

Sincerely,



Bernadette Juarez.
APHIS Deputy Administrator
Biotechnology Regulatory Services
Animal and Plant Health Inspection Service
U.S. Department of Agriculture

August 12, 2020
Date